IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	
TRANSOBTURATOR SLING PRODUCTS	*	MDL Docket No. 2004 4:08-MD-2004(CDL)
LIABILITY LITIGATION	*	ALL CASES

O R D E R

Plaintiffs served a subpoena on Ethicon, Inc. ("Ethicon"), seeking testimony and documents regarding Ethicon's Gynecare TVT Prolene Mesh product ("TVT").[1] Ethicon now moves to quash the subpoena, arguing that (1) the testimony and documents sought are not relevant to the present litigation, (2) the subpoena seeks disclosure of trade secrets and other confidential information, (3) the subpoena imposes an undue burden on Ethicon, and (4) the subpoena seeks to compel unretained expert testimony. For the reasons set forth below, Ethicon's Motion to Quash Subpoena (Doc. 124) is granted in part and denied in part. Specifically, the Court grants Ethicon's motion as to Plaintiffs' attempt to compel it to produce unretained expert testimony. Otherwise, its motion is denied.

BACKGROUND

In the present litigation, Plaintiffs claim that the ObTape Transobturator Sling ("ObTape"), a product designed and manufactured by Mentor for the treatment of female stress urinary incontinence, is defective. Plaintiffs' product liability claims include allegations

[1]Ethicon is a wholly owned subsidiary of Johnson & Johnson, which recently acquired Defendant Mentor Corporation.

of defective design, negligent manufacture, and failure to warn. In support of their defective design claim, Plaintiffs contend that Ethicon's product, TVT, provided a safer feasible alternative design to the ObTape design and that information regarding the design of TVT is relevant to Plaintiffs' design defect claim and also relevant to refute Mentor's alleged contention that its design was as safe as the TVT design.

Plaintiffs' subpoena seeks the following evidence from Ethicon regarding TVT: 1)testimony and documents regarding statements Ethicon made in a TVT product pamphlet entitled "Selecting the Right Mesh: Important properties of implant materials used in urogynecological surgery" ("Pamphlet"); 2) testimony and documents regarding Mentor's 510(k) application to the Food and Drug Administration ("FDA"), in which Mentor claimed that ObTape is the substantial equivalent of TVT; and 3) testimony and documents regarding all testing that was conducted on TVT, including published clinical trials and internal Ethicon studies. Ethicon resists each of these subpoena requests.

DISCUSSION

Under Federal Rule of Civil Procedure 26, Plaintiffs "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). "Relevant information need not be admissible at the trial," but it must be "reasonably calculated to lead to the discovery of admissible evidence." *Id.* A court may grant a nonparty protection from

discovery that seeks confidential or privileged information or would cause undue burden on the nonparty. *Fadalla v. Life Auto. Prods., Inc.*, 258 F.R.D. 501, 504 (M.D. Fla. 2007). A court must quash or modify a subpoena that "requires disclosure of privileged or other protected matter" or "subjects a person to undue burden." Fed. R. Civ. P. 45(c)(3)(A). A court may quash or modify a subpoena that requires "disclosing a trade secret or other confidential research, development, or commercial information" or "disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party." Fed. R. Civ. P. 45(c)(3)(B). If quashing or modifying the subpoena is permissible under Rule 43(c)(3)(B), the Court may nonetheless order production if Plaintiffs show a substantial need for the material "that cannot be otherwise met without undue hardship" and "ensures that the subpoenaed person will be reasonably compensated." Fed. R. Civ. P. 45(c)(3)(C).

To compel compliance with their subpoena, Plaintiffs must first make a threshold showing that the discovery they seek is relevant to their claims or Mentor's defenses. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 164 F.R.D. 623, 625-26 (E.D. Pa. 1996); *accord Transcor, Inc. v. Furney Charters, Inc.*, 212 F.R.D. 588, 591 (D. Kan. 2003); *see also Fadalla*, 258 F.R.D. at 504. If the materials sought are relevant, Ethicon may only avoid compliance with the discovery requests if it can demonstrate that "compliance with the subpoenas

requires the disclosure of privileged or protected information or that compliance presents an undue burden." *Fadalla*, 258 F.R.D. at 504; *see also Mycogen Plant Sci., Inc.*, 164 F.R.D. at 626. To determine whether Plaintiffs' subpoena should be quashed, the Court must weigh Plaintiffs' need for discovery against the burden imposed on Ethicon and Ethicon's interest in keeping the requested information confidential. *Fadalla*, 258 F.R.D. at 504; *Mycogen Plant Sci., Inc.*, 164 F.R.D. at 626.

I. Relevance of TVT Evidence

In this case, Plaintiffs' allegations include a claim that Mentor defectively designed its product ObTape, a polypropylene mesh product implanted in women to treat stress urinary incontinence ("SUI"). Plaintiffs contend that Ethicon's product, TVT, was the "gold standard" for polypropylene mesh products used to treat SUI. Plaintiffs further claim that evidence about TVT is relevant to show that an alternative feasible safer design existed compared to the ObTape design and that such evidence is also relevant to Mentor's "state of the art" defense, to Mentor's claim that it complied with existing industry safety standards, and to Mentor's assertion that there was no feasible safer alternative design for ObTape. Thus, Plaintiffs seek to discover from Ethicon "the feasibility, cost, and consequence to patients of an alternative to ObTape." (Pls.' Resp. to Ethicon's Mot. to Quash Subpoena 7.)

Evidence of a feasible and safer alternative design is clearly relevant to Plaintiffs' design defect claim. *See, e.g., Banks v. ICI Ams., Inc.*, 264 Ga. 732, 735-36, 450 S.E.2d 671, 674-75 (1994) (applying Georgia law); *see also Mitchell v. Fruehauf Corp.*, 568 F.2d 1139, 1144-45 (5th Cir. 1978) (applying Texas law). Therefore, if Plaintiffs' requests are reasonably calculated to lead to the discovery of evidence regarding a feasible design that is safer than the ObTape design, then those requests satisfy Plaintiffs' threshold burden of establishing relevance. Ethicon acknowledges that the design of TVT was an alternative design to ObTape, and the Court finds that Plaintiffs have made a threshold showing that information about the TVT design is generally relevant. *Cf. Standard Fire Ins. Co. v. Broan Nutone, LLC*, No. 2:07CV44-KS-MTP, 2008 WL 5560882, at *6 (S.D. Miss. July 1, 2008) ("A competitor's contemporaneous use of the proposed design alternative for the same purpose in the same consumer market is sufficient evidence to establish a genuine issue of fact as to the existence of a feasible design alternative.").

To avoid compliance with the subpoena, Ethicon must demonstrate that the information sought, while relevant, is privileged in some way or that compliance with the subpoena would be unduly burdensome. Ethicon argues that its internal opinions and research regarding TVT have no place in Plaintiffs' litigation against Mentor because the TVT product itself, as well as information about its cost, is freely available to Plaintiffs and their experts, who can determine for

themselves whether there was a feasible alternative design for ObTape that would have prevented Plaintiffs' injuries. Furthermore, according to Ethicon, there are hundreds of publicly available published studies regarding TVT. The Court addresses these objections, along with the specific relevance of each request, separately as to each request.

II. The Pamphlet

Plaintiffs ask Ethicon for an explanation of various statements made in the "Selecting the Right Mesh" Pamphlet, which Ethicon created to promote TVT. Plaintiffs seek the "basis of published statements" made in the Pamphlet. Ethicon argues that there is no need to compel any further information from Ethicon regarding the Pamphlet because it cited its basis for each of the statements in the Pamphlet itself. Ethicon also asserts that it would be unduly burdensome to ask Ethicon to produce a witness to testify about the Pamphlet, which was created, issued, and used in Europe by persons who were and are located in Europe.

The Court finds that the Pamphlet, a publicly available marketing item, is relevant to the claims and defenses at issue in Plaintiffs' litigation against Mentor. It includes information related to an alternative and allegedly safer design, and it also describes what some in the industry believed to be "the most important mesh properties" for a mesh to treat SUI. The fact that the Pamphlet includes citations to published medical studies that

purportedly support the statements in the Pamphlet does not foreclose additional discovery as to the statements in the Pamphlet and the medical support for those statements. Furthermore, the fact that the most knowledgeable witnesses regarding the Pamphlet are likely located in Europe does not, standing alone, establish undue hardship sufficient to avoid compliance with a subpoena that seeks clearly relevant information, particularly given that the reasonable cost of any such discovery shall be borne by Plaintiffs who seek the information. For these reasons, the Court denies Ethicon's motion to quash with regard to the subpoena requests concerning the Pamphlet.

III. Mentor's Representations in its 510(k) Application

In addition to information regarding the Pamphlet, Plaintiffs seek testimony and documents regarding Mentor's 510(k) application to the FDA, in which Mentor claimed that ObTape is the substantial equivalent of TVT. Specifically, Plaintiffs seek from Ethicon testimony and documents relating to whether ObTape is the substantial equivalent of TVT. (Subpoena Schedule A ¶ 3.) Plaintiffs and Ethicon agree that the question whether a device is the "substantial equivalent" of another device is for the FDA to decide based on the materials submitted to the FDA. Ethicon did not have any role in the 510(k) process for ObTape. Mentor did not consult with Ethicon regarding the 510(k) application, and the FDA did not consult with Ethicon regarding its determination of whether ObTape is substantially equivalent to TVT. Furthermore, Ethicon did not

conduct any studies regarding ObTape. Thus, to the extent that Plaintiffs seek Ethicon's unretained expert opinions regarding Mentor's 510(k) application, which would require Ethicon to analyze data and form a new opinion, that request is denied under Rule 45(c)(3)(B)(ii).[2] However, to the extent that Plaintiffs seek factual information regarding TVT so that Plaintiffs' own experts can determine whether TVT is the substantial equivalent of ObTape, which may be relevant to the feasible alternative design issue, Ethicon has not shown that permitting such discovery would impose an undue burden. Thus, Plaintiffs shall be permitted to discover from Ethicon such factual information regarding TVT.

IV. Ethicon's Studies Regarding TVT

Plaintiffs also seek testimony and documents related to all testing done on TVT. Ethicon responds that more than 475 published clinical trials were conducted. With regard to the published trials, Plaintiffs' main request appears to be for a copy of each study. Ethicon does not contend that these publicly available materials are subject to any trade secret protection, and the Court concludes that they are relevant to the claims and defenses at issue in Plaintiffs' litigation against Mentor because they contain factual data regarding the characteristics and effectiveness of TVT—a product that may be relevant to Plaintiffs' design defect claim. Ethicon has made no

[2]The fact that an Ethicon employee offered a presentation that included criticism of a different Mentor product—Uratape—does not suggest that Ethicon analyzed ObTape to determine whether it is the substantial equivalent of TVT.

showing that it would be unduly burdensome for Ethicon to produce the published studies to Plaintiffs. Though Ethicon initially represented that it would be burdensome to research and produce data gathered over many years, Ethicon apparently had no trouble counting how many published TVT-related studies exist so it could include that number in its briefing. (*See, e.g.*, Ethicon's Br. in Supp. of Mot. to Quash Subpoena 5.) The Court thus concludes that it would not be unduly burdensome for Ethicon to produce the published studies to Plaintiffs. Accordingly, Ethicon shall produce the published studies, with the reasonable cost of the production to be borne by Plaintiffs.

Plaintiffs also seek internal Ethicon documents regarding testing of TVT. Ethicon contends that these documents are confidential and contain trade secrets. Ethicon represents that there are fifty-five internal studies—none of which involved ObTape—that describe Ethicon's manufacturing, sterilization, testing, and evaluation processes. Ethicon asserts that this information has been kept confidential and that it is the type of information that would be highly valuable to a competitor. To date, Ethicon has not provided to the Court or to Plaintiffs a privilege log or any other information regarding the internal documents except conclusory and generalized assertions that the studies qualify as trade secrets, so it is not possible for the Court to make a thorough factual

determination as to whether the documents are, in fact, trade secrets that have been kept confidential.

Even if the internal documents did qualify as trade secrets, Plaintiffs have a substantial need for the documents. Plaintiffs assert that studies regarding TVT are relevant to Mentor's argument that there was no feasible safer alternative design for ObTape and Plaintiffs' argument that there was. As previously explained, the information about TVT—which Mentor claimed in its 510(k) application to the FDA is the substantial equivalent of ObTape—is relevant to the claims and defenses in this litigation. Plaintiffs cannot obtain the information from another source. Moreover, the present record does not reveal the basis for any contention that a need presently exists to protect the disclosure of Ethicon information from Mentor since both entities are currently owned by the same parent company, and thus presumably are no longer competitors. As to the protection of the information from other competitors, such protection can be adequately accomplished by subjecting the production of the materials to the restrictions contained in the existing protective order in this case. For these reasons, the Court concludes that Ethicon should produce the internal TVT studies to Plaintiffs, subject to the protective order in effect in this MDL proceeding.[3]

[3]The Court's ruling should not be interpreted to mean that a nonparty's privileged materials are subject to disclosure to a competitor without close judicial scrutiny. The Court's decision in this case is strongly influenced by the fact that Mentor and Ethicon are related entities owned by the same parent company and are not competitors. If that were not the case, the Court might have reached a different

CONCLUSION

Ethicon's Motion to Quash Subpoena (Doc. 124) is granted in part and denied in part. As discussed above, Ethicon shall not be required to provide unretained expert opinions regarding Mentor's 510(k) application but shall be required to comply with the subpoena in all other respects. The protective order in effect in this MDL proceeding shall apply to documents and testimony produced by Ethicon in response to the subpoena.

Ethicon shall produce documents responsive to the subpoena within fourteen days of the date of this Order. Ethicon shall have thirty days from the date of this Order to make witnesses available for depositions. The Court expects the parties to cooperate in accomplishing this discovery in a reasonably expedited manner. Any disputes should be identified as soon as possible and brought to the Court's attention by informing the Court that a telephone conference is necessary to resolve any issues that cannot be resolved by the parties.

IT IS SO ORDERED, this 14th day of January, 2010.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE

conclusion. *Cf. Martin v. The Budd Co.*, 713 N.E.2d 1128, 1131 (Ohio Ct. App. 1998) (finding that nonparty was not required to produce trade secret information as evidence of feasible alternative design in case against its competitor).